(b) *Sterility.* A sterility test shall be performed on the contents of final containers of each lot of each product as prescribed in §610.12 of this chapter.

(c) *Pyrogens.* A pyrogen test shall be performed on the contents of final containers of each lot of each product as prescribed in §610.13(b) of this chapter.

(d) *Anaphylaxis.* An anaphylactic test shall be performed on the contents of a sufficient number of final containers of each lot of each product to perform the test as follows:

(1) The contents of one final container shall be injected intraperitoneally into each of 10 normal guinea pigs.

(2) After 3 weeks, each guinea pig shall be challenged intravenously with a 0.2-milliliter sample of the same product.

(3) None of the 10 sensitized guinea pigs shall exhibit anaphylactic shock.

§ 680.24 General requirements.

(a) *Processing.* (1) The processing method shall be one that has been shown consistently to yield a specific, potent final product, free of properties that would affect the product for its intended use throughout the dating period.

(2) Only material that has been fully processed, sterile filtered into a single vessel, and thoroughly mixed in that vessel shall constitute a lot.

(3) Each lot shall be filled in a single continuous operation.

(b) *Total nitrogen.* Blood Group Substances shall contain not more than 8 percent total nitrogen when determined on moisture-free and ash-free samples.

(c) *Preservative.* A preservative shall not be incorporated into bulk manufactured Blood Group Substance or into final containers. However, phenol may be present as a residual from manufacturing.

(d) *Final containers.* Final containers shall be sterile, pyrogen free, colorless, and transparent. The contents of the final container shall not exceed 1 milliliter of product containing not more than one immunizing dose of Blood Group Substance powder.

(e) *Date of manufacture.* The date of manufacture shall be the date the manufacturer initiates the last valid potency test that is reported on a protocol and submitted to the Director, Center for Biologics Evaluation and Research.

(f) *Dose.* A single human dose for intramuscular, subcutaneous or intradermal injection shall not exceed the contents of a final container.

[44 FR 20674, Apr. 6, 1979; 48 FR 13026, Mar. 29, 1983, as amended at 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

§ 680.25 Labeling.

In addition to the labeling requirements of §610.62 of this chapter and in lieu of the requirements in §§610.60 and 610.61 of this chapter, the following shall appear on the label of Blood Group Substances:

(a) *Label affixed to each final container.* (1) Proper name of the product.

(2) Name, address (including zip code), and license number of the manufacturer.

(3) Lot number.

(4) Expiration date.

(5) The statement ''ONE IMMUNIZING DOSE''.

(6) Recommended storage temperature.

(7) The statement ''SEE DIRECTIONS FOR USE''.

(b) *Container not enclosed in a package.* If the final container is not enclosed in a package, e.g., the container is enclosed only in an unlabeled shipping carton, all information required for the package label in paragraph (c) of this section shall accompany and be attached to each final container.

(c) *Package label.* (1) Proper name of the product.

(2) Name, address (including zip code), and license number of the manufacturer.

(3) Lot number.

(4) Expiration date.

(5) The statement ''CONTAINS NO PRESERVATIVE''.

(6) Number of containers, if more than one.

(7) The statement ''DERIVED FROM PORCINE (OR EQUINE) STOMACHS'', as applicable.

(8) The statement ''EACH FINAL CONTAINER CONTAINS ONE IMMUNIZING DOSE''.

(9) Recommended storage temperature.